DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1999

Mr. Raji Juma
MYCO Medical Supplies, Inc.
101 Rose Valley Woods Drive
Cary, North Carolina 27513

Re: K982646
Trade Name: Ailee Sutures and Ailee Needles
Regulatory Class: II
Product Code(s): GAL Suture, Absorbable, Natural
GAP Suture, Nonabsorbable, Silk
GAS Suture, Nonabsorbable, Synthetic, Polyester (PE)
GAW Suture, Nonabsorbable, Synthetic, Polypropylene (PP)
GAR Suture, Nonabsorbable, Synthetic, Polyamide (Nylon)
GAM Suture, Absorbable, Synthetic, PolyGlycolic Acid (PGA)
GAN Suture, Absorbable, Synthetic
HMN Suture, Nonabsorbable, Ophthalmic
GAO Suture, Nonabsorbable

Dated: April 6, 1999
Received: April 6, 1999

Dear Mr. Juma:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosures) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Monday, December 11, 1989 (Vol. 54, No. 236, Pages 50737 and 50738). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Ailee Chromic Gut, Catgut plain, and Polygolycolic acid (PGA) Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

2. The Ailee Chromic Gut and Catgut plain sutures may not be manufactured from any material other than serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacturing of the Ailee surgical suture. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed change(s).

3. The Ailee Polygolycolic acid (PGA) Surgical Sutures may not be manufactured from any material other than homopolymers and copolymers made from glycolide and/or L-lactide. Any deviation of the polymer composition or processing as described in this 510(k) notification must be sumitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed changes. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacturing of the Ailee PGA surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and FDA clearance prior to commercial distribution of the modified device.

4. The Ailee Silk, Polyester, Nylon, and Polypropylene Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

5. The Ailee Silk Surgical Suture may not be manufactured from any material other than multifilamentous fibers composed of fibroin, an organic protein that is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Ailee Silk Surgical Suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

6. The Ailee Polyester Surgical Suture may not be manufactured from any material other than high molecular weight fibers composed of long chain linear polyester having recurrent aromatic rings as an integral component. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation

of sterilization procedures used in the manufacture of the Ailee surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

7. The Ailee Nylon Surgical Suture may not be manufactured from any long chain aliphatic polymers other than nylon 6 and/or nylon 6,6. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Ailee Nylon surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

8. The Ailee Polypropylene Surgical Sutures may not be manufactured from any material other than a long chain polyolefin polymer known as polypropylene. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Polypropylene surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of these devices are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4595. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K982646

510 (k) Number (if known): K982646

Device Name: Chromic Gut

Indication For Use:

Chromic Gut surgical sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but NOT for use in cardiovascular and neural tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K982646

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510 (k) Number (if known): K982646

Device Name: Catgut plain

Indication For Use:

Catgut plain surgical sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but NOT for use in cardiovascular and neural tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

510 (k) Number (if known): K982646

Device Name: Polyglycolic acid sutures

K982646/S3

Indication For Use:

Polyglycolic acid sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but NOT for use in cardiovascular and neurological tissues.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

S'k
32

K982646

510 (k) Number (if known): K982646

Device Name: Silk sutures

Indication For Use:

Silk sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

K982646

510 (k) Number (if known): K982646

Device Name: Polyester sutures

Indication For Use:

Polyester sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

K982646

510 (k) Number (if known): K982646

Device Name: Nylon sutures

Indication For Use:

Nylon sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

K982646

510 (k) Number (if known): K982646

Device Name: Polyproylene sutures

Indication For Use:

Polyproylene sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)